

## REMARKS

### *Attorney Docket Number*

Please note that the attorney docket number for this application has changed to 401865.

### *Examiner Interview*

Applicants thank Examiners Susan Tran and Dr. Gollamudi Kishore for the courtesy extended to Applicants' representatives Xavier Pillai and Len S. Smith in the in person interview conducted on October 9, 2002 at the U.S. Patent and Trademark Office. The substance of the interview is recorded in the Interview Summary, which already is of record. Specific issues discussed in the Interview are further addressed below.

### *The Claim Amendments*

Claims 16-32 are hereby substituted with new claims 33-50. The new claims, which are directed to the production of fenofibrate microparticle compositions, according to particular aspects of Applicants' invention, and the products of such methods, are offered to expedite allowance. Claims corresponding to the compositions of Applicants invention, *per se*, are not included in new claims 33-50. However, Applicants reserve the right to pursue such claims in a related application, and the fact that such claims are not included in new claims 33-50 in no way constitutes a surrender of Applicants' rights in such aspects of their invention.

The new claims are supported by the originally filed specification and claims. For example, new claim 33 is derived from claim 26 and finds further support at, e.g., pages 5 and 6 of the application. New claim 34 is derived from claims 7, 10, and 23, and finds additional support at, e.g., page 1, 2nd paragraph and page 6, 1st paragraph of the application. New claims 35 and 36 are derived from claims 22 and 25, respectively. New claim 37 is derived from aspects of claims 16 and 26. Support for new claim 38 can be found at, e.g., page 4, 3rd full paragraph of the application. New claims 39-45 are derived from claims 31, 32, and 17-21, respectively. Claims 46-50 similarly find support in these portions of the originally filed specification and claims. In view of the support for the new claims in the original claims and specification, no new matter is added by the claim amendments.

Claims 33-50 are pending. Claim 33 is the only independent claim. As new claims 33-50 replace previously pending claims 16-32, no document specifying changes to the claims is required (see 37 C.F.R. § 1.121 (c)(ii)).

*The Office Action*

The Office Action rejected claims 16-25, under 35 U.S.C. § 112, first paragraph, as allegedly "containing matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention." The Office Action further indicated that claims 1-7 are rejected under 35 U.S.C. § 103(a) as allegedly obvious.

The Office Action also entered a contingent species election, calling for Applicants to elect a species from (a) hard or soft gel capsules; (b) tablets; (c) granules; or (d) powders dried by lyophilization, fluid or spray drying, in the event that no generic claim is allowed. The Office Action acknowledged that claim 16 was generic to the proposed species.

*The Section 112 Rejections*

The Office Action rejected claims 16-25 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement. Specifically, the Office Action rejected claims 16-25 for including the phrase "fenofibrate microparticles of irregular, non-spherical or spherical shapes," and further rejected claims 26-32 for including the phrase "a process of preparing in water," which the Office Action alleged was not described in the specification in a way so as to convey that the inventors possessed the claimed invention at the time of filing. While not agreeing with the Office Action's rejection of these claims, Applicants submit that because none of these phrases appear in new claims 33-50, these rejections are now moot.

The Office Action further rejected claim 31 under Section 112 due to its inclusion of the phrase "above the critical micelle concentration." This feature of Applicants' invention, which is embodied in new claim 39, finds support at, e.g., page 4, lines 24-27 of specification and original claim 13. It is well accepted that original claims of an application constitute their own description and can convey that an applicant invented the subject matter of what was claimed. See, e.g., *In re Koller*, 204 USPQ 702 (CCPA 1980). Thus, the specification and original claims evidence Applicants' "possession" of the subject matter of claim 31 at the time the subject

application was filed. Accordingly, Applicants respectfully submit that this rejection of claim 31 under Section 112 should be withdrawn. The Examiner is encouraged to contact Applicants' representative if further clarification regarding such support or the legal standards of the written description requirement would be helpful.

In the Interview of October 9, 2002, the Examiners expressed concern with respect to whether mannitol was required to produce fenofibrate microparticles in the inventive method, based on the fact that mannitol was included in Examples 1-5 in the subject application. Applicants submit herewith a Declaration of Dr. Robert A. Snow under 37 C.F.R. § 1.132. As set forth in paragraph 3 of Dr. Snow's Declaration, fenofibrate microparticles can be produced by the presently claimed method with or without the presence of mannitol. Thus, the recitation of mannitol in new claim 33 is unnecessary.

In view of the evidence submitted herewith, Applicants submit that claims 33-50 are in proper form with respect to the requirements of Section 112.

#### *The Obviousness Rejection*

The Office Action rejects claims 1-7 as allegedly obvious over U.S. Patent 5,776,495 (Duclos et al.) in view of U.S. Patent 4,963,367 (Ecanow).

The subject application is a continued prosecution application (CPA) filed on February 21, 2002. According to the MANUAL OF PATENT EXAMINING PROCEDURE (M.P.E.P.) (8th Edition - 2001), a CPA is treated as an "amended" application modified by all amendments entered prior to the CPA filing. See M.P.E.P. § 201.06(d). Accordingly, as discussed in the Examiner Interview, claims 1-7 were cancelled prior to the issuance of the most recent Office Action and the Office Action's rejection of *these* claims clearly is in error.

As Applicants' representatives discussed with the Examiners in the Interview, it appears to Applicants that the Office Action intended to reject the previously pending composition claims, i.e., claims 16-25, which were derived from original claims 1-7, as opposed to claims 1-7. Correspondingly, it appears that the Office Action intended to allow claims 26-32, which were derived from original claims 8-15, which were similarly directed to a method of preparing fenofibrate microparticles in the presence of a phospholipid and a surfactant. Such a conclusion is supported by the record, inasmuch as the Office has already correctly admitted that neither the Duclos '495 patent, nor the Ecanow '367 patent, teach a

method of preparing fenofibrate microparticles by a method that includes preparing a mixture comprising fenofibrate particles, a phospholipid, and a nonphospholipid surfactant, and applying energy to such a mixture to obtain fenofibrate microparticles (see, e.g., Office Action of September 18, 2000 - page 4) (a later Section 103 rejection involving these references in combination with U.S. Patent 5,091,187 (Haynes) appears to have been overcome by Applicants' earlier remarks (see Office Action of January 30, 2002 and Applicants' response thereto)).

Applicants note that during the Interview, Dr. Kishore indicated to Applicants' representatives that should the Office Action interpret the obviousness rejection in the Office Action differently than Applicants, the Office would hereafter issue a non-final Office Action clarifying the Office's position, should any such Office Action be required. As expressed at the Interview, Applicants fully encourage the Office to take the appropriate steps to consider the patentability of the presently claimed method in view of any art that the Examiners feel may be relevant so that all possible issues are resolved during prosecution of these claims.

As new claims 33-50, like original claims 8-15, are directed to Applicants' novel methods of preparing fenofibrate microparticles, which the Office has acknowledged are patentable over the cited references, Applicants respectfully solicit an acknowledgment that these claims are allowable as free of the prior art.

#### *Species Election*

In response to the contingent species election requirement, Applicants elect tablets produced from fenofibrate microparticles, if a generic claim is not allowed. Claim 45 reads on tablets. Claim 33 is generic to claim 45.

#### *Conclusion*

The application is considered in good and proper form for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Len S. Smith", is written over a horizontal line.

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